

REMARKS/ARGUMENTS

Claim 4 is amended to clarify that a solvate of olanzapine may be used as a starting material of the process of independent claim 1. Claim 23 is amended to clarify that the pharmaceutical composition recited therein is in solid state. Support for the amendments can be found at, for example, paragraphs 0032-0033 and 0079-0080 of the published specification. No new matter is added. Entry of the above amendments is respectfully requested. Upon entry of the amendments, claims 1-28 are pending. Reconsideration of the above amendments and the following remarks is respectfully requested.

Applicants gratefully acknowledge that claims 6-9, 12-22, 24, and 26-28 are allowed.

Anticipation Rejection of Claims 1-5, 10, 11, and 25 in view of Bunnell et al. under 35 U.S.C. §102(b)

Claims 1-5, 10, 11, and 25 stand rejected under 35 U.S.C. §102(b) as being anticipated by Bunnell et al., U.S. Patent 5,703,232. Applicants respectfully traverse.

Claims 1-5 are directed to a process for the preparation of form I of olanzapine, comprising the step of crystallizing olanzapine in a solvent mixture which comprises 2-propanol.

In contrast, Bunnell describes the preparation of the solvate of olanzapine, not olanzapine itself or crystalline form I of olanzapine. As stated in Bunnell at col. 1, lines 63-64, "the present invention provides a new method for preparing a lower alcohol solvate of olanzapine." Form I of olanzapine recited in the claims 1-5 is a polymorph, rather than a pseudopolymorphic form, i.e., a solvate of olanzapine. See, for example, abstract, paragraphs 0001, 0028, and 0034 of the published specification. Accordingly, Bunnell does not anticipate claims 1-5 of the present application.

The Examiner appears to misunderstand that the final olanzapine Form I product made in accordance with the process of claims 1-5 is a solvate of olanzapine, based on claim 4, which

depend from claim 1. To clarify that the solvate of olanzapine is only a starting material in the process of claim 1, Applicants have amended claim 4 as follows:

4.(Currently Amended) Process according to claim 1, wherein the olanzapine used in the crystallizing step is ~~used in form of~~ a solvate of olanzapine.

Based on the above amendment, dependent claim 4 only indicates that a solvate of olanzapine may be used as a starting material of the process of independent claim 1; it does not indicate that the final olanzapine form I is an olanzapine solvate, as incorrectly understood by the Examiner. *See* also paragraphs 0032-0033 and 0079-0080 of the published specification.

Regarding claims 10-11, which are directed to 2-propanol solvate of olanzapine, although Bunnell discloses methanol, ethanol, and 1-propanol solvates (*See*, for example, columns 5-7, Tables 1-3 and columns 15-16, Examples 1-6), it does not disclose, suggest, or teach a 2-propanol solvate of olanzapine and process of making thereof. Therefore, claims 10-11 are not anticipated by Bunnell under 35 U.S.C. § 102(b).

Nor would Bunnell render the solvate recited in claims 10-11 obvious, because as stated in Bunnell, “The formation of solvates is known to be an individualistic effect. The ability of a given compound to form a solvate is not predictable, to Applicant’s knowledge. Further, the beneficial utility of such solvates is particularly surprising.”

Claim 25 is directed to a process for preparing anhydrous forms of olanzapine by drying at least one solvate according to claim 10. As stated above in connection with claim 10, Bunnell does not anticipate or render obvious the solvate recited in claim 10. Therefore, for at least the same reasons discussed above in connection with claim 10, claim 25 is also patentable in view of Bunnell.

Withdrawal of the rejection of claims 1-5, 10, 11, and 25 in view of Bunnell under 35 U.S.C. §102(b) is, therefore, respectfully requested.

Anticipation Rejection of Claim 23 in view of Charkrabarti et al. under 35 U.S.C. §102(b)

Claim 23 is rejected under 35 U.S.C. §102(b) as being anticipated by Charkrabarti et al., U.S. Patent 5,229,382.

Claim 23 is directed to a pharmaceutical composition, which comprises crystalline form A of olanzapine characterized by a particular x-ray diffraction pattern.

The Examiner states that because claim 23 fails to specifically claim a solid pharmaceutical composition to retain characteristics of a polymorph, Applicants cannot rely on the XRD pattern recited in claim 23 to distinguish from Charkrabarti et al. In response, Applicants have now amended claim 23 to specify that the pharmaceutical composition be in solid form, as suggested by the Examiner. Because Charkrabarti does not disclose, teach, or suggest crystalline form A recited in claim 23, it cannot anticipate claim 23 under 35 U.S.C. §102(b). Accordingly, it is respectfully requested that the rejection of claim 23 under 35 U.S.C. §102(b) as being anticipated by Charkrabarti be withdrawn.

If any additional fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

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